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08/429,494	04/26/95	WILLIAMSSON	A 003300-336

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ART UNIT	PAPER NUMBER
1313	8

DATE MAILED:

08/06/96

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents.

**A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS ACTION IS SET
TO EXPIRE 3 MONTHS, DAYS FROM THE DATE OF THIS LETTER.**

Office Action Summary

Application No. 08/429,494	Applicant(s) Anders Williamsson et al.
Examiner Harold Pyon	Group Art Unit 1313



Responsive to communication(s) filed on May 15, 1996

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 9-15 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 9-15 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the ~~_____~~ Notice of Draftsperson's Patent Drawing Review, PTO-948. paper #4

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing ~~correction~~, filed on May 15, 1996 is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Claim Rejections - 35 USC § 112

1. Claims 10-12 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 10, line 2, the phrase "two substantially planar surface of said body member" is not clear. It is unclear what the two planar surface is referring to. Is the planar surface referring to entire inner surface of the body?

In claim 11, line 2, the phrase "distance between the two substantially planar surfaces" is unclear. What is the difference between the "planar surfaces" and "inner surface of the body"? It is also unclear what is the difference between "the distance between the two substantially planar surfaces" and "the distance between the inner surfaces of the body member at the measuring zone".

Clarification or/and correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 9-10,13 are rejected under 35 U.S.C. § 102(b) as being anticipated by Hillman et al.

Hillman et al. teach an integral capillary flow device comprising a body member (Fig. 2A, #50) provided with a cavity (Fig. 2A, #58, receiving chamber), the cavity being defined by two opposing inner surfaces of the body member (Fig. 2B, #52, #54, column 19, lines 42-43) and a portion of the cavity defining a measuring zone (Fig. 2B, #76, column 20, lines 33-34) within the body member 50, the cavity having an inner peripheral zone at which is located a channel (Fig. 2B, #62), the channel having opposite ends that communicate with the exterior of the microcuvette (Fig. 2B #74), the channel having a higher capillary force than the measuring zone (Fig. 2B, #62, #60, column 19, line 66 to column 20, line 2), the body member having an outer peripheral edge provided with a sample inlet (Fig. 2A, #64) through which a sample is drawn into the body member, the sample inlet 64 being in communication with the channel 66 and the channel being in communication with the measuring zone 76, wherein the channel is defined by an inner end wall of the inner peripheral zone (Fig. 2B, end of #62) and two substantially planar surfaces of the body member (Fig. 2B, #52, #54), and wherein the cavity has a predetermined volume (Fig. 2B, #58).

4. Claims 9-10, 13 are rejected under 35 U.S.C. § 102(b) as being anticipated by Fielding.

Fielding teaches a capillary specimen holder comprising a body member provided with a cavity which is defined by two opposing inner surface of the body member (column 1, lines 13-17)

and a portion of cavity defining a measuring zone within the body(column 1, lines 18-20), the cavity having an inner peripheral zone at which is located a channel(Fig.1, between #13 and #14), the channel having opposite ends that communicate with the exterior of the microcuvette(Fig.2, left end of #17, Fig.3, #17), the channel having a higher capillary force than the measuring zone(channel #13 has a higher capillary force than channel #17), the body member having an outer peripheral edge provided with a sample inlet through which a sample is drawn into the body member(Fig.2, #13), the sample inlet 13 being in communication with the channel and the channel being in communication with the measuring zone(Fig.2, #17); wherein the channel is defined by an inner end wall of the inner peripheral zone(Fig.2, #13,#14,#17) and two substantially planar surface of the body member(column 2, lines 41-44); wherein the cavity has a predetermined volume(Fig.3, predetermined space #17). Note that the smaller area has a higher capillary force than the larger area in the flow dynamic.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

5. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 148 USPQ 459, that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or unobviousness.

7. Claims 11-12,14-15 are rejected under 35 U.S.C. § 103 as being unpatentable over Hillman et al. in view of Cottingham('695) and Mochida.

Hillman et al. teach an integral capillary flow device as described above(see Hillman et al. *supra*).

Hillman et al. fail to disclose the specific distance between the two planar surfaces and inner surfaces of the body member at the measuring zone, the distance between the two planar surfaces of the body member increases in a direction extending away from the inner end wall of the inner peripheral zone, and a predetermined amount of the dry reagent in the cavity.

Mochida teaches that the channel may be provided with a reagent-attached area wherein a reagent is tentatively attached so that the reagent may dissolve into the fluid flowing over the area (abstract). Cottingham also teaches the predetermined amount of the dry agent in the channel for the purpose of testing a additional test (Fig. 8A & 8B, column 5, lines 44-47).

As to the specific distance between the inner surfaces of the body member at the measuring zone and the relative distance between the two planar surfaces of the body member and inner surfaces of the body member at the measuring zone, the specific distance or relative distance between the inner surfaces of the body member at the measuring zone would be readily determined through routine experimentation by one having ordinary skill in the art depending on the desired end result. Normally, it is to be expected that a change in distance between the inner surfaces of the body member, or in size, or in shape, would be an unpatentable modification. Under some circumstance, however, changes such as these may impart patentability to an apparatus if the particular distance or size or shape claimed produce a new

and unexpected result which is different in kind and not merely in degree from the results of the prior art. *In re Rose*, 105 USPQ 237 CCPA 1955. *In re Reese*, 129 USPQ 402. *In re Dailey et al.*, 149 USPQ 47 CCPA 1966.

It would obvious to one of ordinary skill in the art at the time applicants' invention was made to have modified Hillman with a well known dry chemical in the channel as taught by Mochida and Cottingham in order to determine the content of the sample.

8. Claims 11-12,14-15 are rejected under 35 U.S.C. § 103 as being unpatentable over Fielding in view of Cottingham('695) and Mochida.

Fielding teaches a capillary specimen holder as described above(see Fielding *supra*).

Fielding fails to disclose the specific distance between the two planar surfaces and inner surfaces of the body member at the measuring zone, the distance between the two planar surfaces of the body member increases in a direction extending away from the inner end wall of the inner peripheral zone, and a predetermined amount of the dry reagent in the cavity.

Mochida teaches that the channel may be provided with a reagent-attached area wherein a reagent is tentatively attached so that the reagent may dissolve into the fluid flowing over the area(abstract). Cottingham also teaches the predetermined amount of the dry agent in the channel for the purpose of testing a additional test(Fig.8A & 8B, column 5, lines 44-47).

As to the specific distance between the inner surfaces of the body member at the measuring zone and the relative distance between the two planar surfaces of the body member and inner surfaces of the body member at the measuring zone, the specific distance or relative distance between the inner surfaces of the body member at the measuring zone would be readily determined through routine experimentation by one having ordinary skill in the art depending on the desired end result. Normally, it is to be expected that a change in distance between the inner surfaces of the body member, or in size, or in shape, would be an unpatentable modification. Under some circumstance, however, changes such as these may impart patentability to an apparatus if the particular distance or size or shape claimed produce a new and unexpected result which is different in kind and not merely in degree from the results of the prior art. *In re Rose*, 105 USPQ 237 CCPA 1955. *In re Reese*, 129 USPQ 402. *In re Dailey et al.*, 149 USPQ 47 CCPA 1966.

It would obvious to one of ordinary skill in the art at the time applicants' invention was made to have modified Fielding with a well known dry chemical in the channel as taught by Mochida and Cottingham in order to determine the content of the hemoglobin.

9. Applicant's arguments with respect to claims 9-15 have been considered but are deemed to be moot in view of the new grounds of rejection.

Serial Number: 08/429,494
Art Unit: 1313

-9-

10. The remaining references cited in the previous Office action remain cited for the showings previously indicated.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Harold Pyon whose telephone number is (703) 308-4251.


HAROLD PYON
PATENT EXAMINER
GROUP 1300

August 1, 1996